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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,286	03/01/2002	Robert D. Torgerson	D0188/7135	3327
7590	04/22/2005		EXAMINER	
Elizabeth R. Plumer Wolf, Greenfield & Sacks, P.C. 600 Atlantic Avenue Boston, MA 02210			BUI, VY Q	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 04/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

5P

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/086,286	TORGERSON ET AL.	
	Examiner	Art Unit	
	Vy Q. Bui	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 22 February 2005.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-14 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

**DETAILED ACTION*****Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 1-3, 6-10, and 13-14 are rejected under 35 U.S.C. 102(e) as being anticipated by MECHANIC (5,332,475).

As to claims 1-3, 6-10, and 13-14, MECHANIC (col. 2, ll. 42-68; col. 3, ll. 1-2; col. 4, ll. 19-53) discloses using collagen fibrils or finely ground bovine skin collagen in a cross-linking process not subjected to an acid dissolution to make collagen fiber/fabric/matrix to be used inside a human being as an implant. Inherently, the product to be used inside a human body must have been sterilized. Specially, MECHANIC (col. 4, lines 54-64; claim 2, lines 1-8) discloses proteinaceous material/collagen fibril(s) being suspended in an aqueous media such as water (having a pH of from about 6.8 to 8.6) to avoid denaturalization of the collagen.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 4-5 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over MECHANIC (5,332,475).

As to claims 4 and 11, MECHANIC discloses a cross-linked collagen product having substantially all limitations in the claims except for a bulk density from 1.5 to about 3.5 lbs/cubic ft. However, MECHANIC (col. 4, ll. 25-30) discloses that one can select a collagen source according to one's intended use of the cross-linked collagen product. It would have been obvious to one of ordinary skill in the art to select a specific range of density such as the range as claimed to fit one's need/application.

As to claims 5 and 12, MECHANIC discloses a cross-linked collagen product having substantially all limitations in the claims except for a hemostatic agent. It is well known to incorporate a hemostatic agent to a collagen product such as a fabric/matrix/pad to enhance hemostatic effect. It would have been obvious to one of ordinary skill in the art to incorporate a hemostatic agent to MECHANIC collagen product so as to enhance the hemostatic effect of the MECHANIC collagen product.

### ***Response to Arguments***

Applicant's arguments filed 2/22/2005 have been fully considered but they are not persuasive.

MECHANIC-'475 (col. 4, lines 38-64; claim 2, lines 1-8) clearly discloses a process comprising using a proteinaceous such as a finely ground bovine skin collagen suspended in a buffer media (which has pH in a range of 6.8 to 8.6) such as water (pH about 7) to avoid denaturation of the collagen (MECHANIC-'475, col. 7, lines 18-22). The Applicants argued that water is not a buffer medium. However, water having a pH about 7 (neutral), which is well within a pH range of 6.8-8.6 as disclosed by Mechanic-'475, must be considered as a buffer medium. Further, Mechanic-'475 (col. 4, lines 50-64) clearly specify water as a suitable medium

for suspension a proteinaceous material without denaturation effect to the proteinaceous material.

In the claimed invention, there is no language/or feature to distinguish the present invention over MECHANIC-'475 reference.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 703-306-3420. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott or Shaver can be reached on 703-308-0858. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



04/18/2005  
Vy Q. Bui  
Primary Examiner  
Art Unit 3731